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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,022

03/22/2004

Jeffrey S. Kiel

455-024

1967

1009 7590 01/02/2009  
KING & SCHICKLI, PLLC  
247 NORTH BROADWAY  
LEXINGTON, KY 40507

EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

01/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,022	<b>Applicant(s)</b> KIEL ET AL.	
	<b>Examiner</b> Taylor Victor Oh	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-24 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-10,18,19,25 and 27 is/are rejected.
- 7) ☒ Claim(s) 11-17,20-21,26,28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **Final Rejection**

### The Status of Claims

Claims 1-2 and 5-28 are pending.

Claims 1-2 , 5-10, 18-19, 25, and 27 are rejected.

Claims 11-17,20-21,26, 28 are objected.

Claims 22-24 are allowable.

### **Claim Rejections - 35 USC § 103**

Applicants' argument filed 10/20/2008 have been fully considered but are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**The rejection of Claims 1-2 , 5-10, 18-19, 25, 27 under 35 U.S.C. 103(a) as being unpatentable over Bryans et al (US 7,141,606) in view of Berge et al (J. of Pharmaceutical Sciences, 66,no. 1, Jan, 1977, p.1-19).**

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The rejection of Claims 1-2 ,5-10,18-19,25, and 27 under 35 U.S.C. 103(a) as being unpatentable over Bryans et al (US 7,141,606) in view of Berge et al (J. of Pharmaceutical Sciences, 66,no. 1, Jan, 1977, p.1-19) has been maintained with reason of record filed on 9/24/07.

#### Applicants' Argument

Applicants argue the following issues:

- a. Bryan et al disclose gabapentin (not gabapentin tannate) for treating insomnia; there is no mention of a tannate salt of gabapentin in Bryan et al;
- b. Berge et al disclose a laundry list of FDA approved salts including tannate at a uasage of 0.88 % compared to a usage of 42.98 % for hydrochloric acid salts with no mention of gabapentin acid;
- c. Berge et al explicitly disclose that choosing the appropriate salt is a “ very difficult task “ and that “ there is no reliable way of predicting the influence of a particular salt species on the behavior of the patent compound, thus being unable to provide a reasonable expectation of success for the claimed combination.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first and third arguments, the Examiner has noted applicants' arguments. However, regarding the reasonable expectation of success for the combined prior

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art, Bryans et al expressly discloses gabapentin derivatives having the following uses(see col. 1, lines 22-26 ):

protective effect against cramp induced by thiosemicarbazide; protective action against cardiazole cramp; the cerebral diseases, epilepsy, faintness attacks, hypokinesia, and cranial traumas; and improvement in cerebral functions. The

Furthermore, the gabapentin has a nitrogen and a carboxyl group in the chemical compound and its salt possible forms are described in the followings (see col. 10 ,lines 33-37):

Since amino acids are amphoteric, pharmacologically compatible salts when R is hydrogen can be salts of appropriate inorganic or organic acids, for example, hydrochloric, sulphuric, phosphoric, acetic, oxalic, lactic, citric, malic, salicylic, malonic, maleic, succinic, methanesulfonic acid,

Moreover, Berge et al describes potentially useful salts in the pharmaceutical compounds in which the salt is formed by an acid-base reaction involving either a proton-transfer or neutralization reaction (see page 2 , left col. at the middle paragraph). Furthermore the table I shows various FDA-approved commercially marketed salts among which the tannate is displayed as one of the potential candidates for the pharmaceutical compounds.

Bryans et al expressly discloses that it seems reasonable to form the organic salt forms of gabapentin for sleep disorders (see col. 10 ,lines 33-37). Berge et al expressly describes various FDA-approved commercially marketed salts among which the tannate is displayed as one of the potential candidates for the pharmaceutical compounds. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to use the tannate for the salt of gabapentin for sleep disorders ; this is because Berge et al expressly teaches that one of the

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FDA-approved commercially marketed salts can be the tannate. Therefore, applicants' argument is not persuasive.

Second, regarding the second argument, the Examiner has noted applicants' arguments. However, regardless of how low the % of usage of the tannate is in comparison with the % of that of hydrochloric acid salts, the main issue is that FDA does approve the salt of tannate in commercially marketed salts for the pharmaceutical formulations. Furthermore, in the pharmaceutical industry, formulations must be tested by routine procedures to verify expected properties. There is nothing to change the fact that the Berge' et al table I does show that the tannate is displayed as one of the potential salt-candidates for the pharmaceutical compounds. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to use the tannate for the salt of gabapentin for sleep disorders ; this is because Berge et al expressly teaches that one of the FDA-approved commercially marketed salts can be the tannate. Therefore, applicants' argument is not persuasive.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taylor Victor Oh/  
Primary Examiner, Art Unit 1625

12/30/08

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